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Dated: 7/25/07 Signature: Andrea MacVarish
(Andrea MacVarish)

Docket No.: 2002(203121)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Dwayne Kirk

Application No.: 10/683,611 Confirmation No.: 5103

Filed: October 10, 2003 Art Unit: 1638

For: METHODS AND COMPOSITIONS FOR STABLE TRANSGENIC PLANT PHARMACEUTICALS AND THEIR USE AS CONTRACEPTIVES

Examiner: V. Kumar

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

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Commissioner for Patents
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Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

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In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 04-1105 in the amount of $180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 2002(203121). A duplicate copy of this paper is enclosed.

Dated: July 25, 2007

Respectfully submitted,

By _____

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Attorney Docket Number	2002(203121)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Arakawa T, Yu J, Chong DK, Hough J, Engen PC, Langridge WH: "*A plant-based cholera toxin B subunit-insulin fusion protein protects against the development of autoimmune diabetes*"; Nat Biotechnol 16: 934-8 (1998).	
	CB	Arikawa, J., K. Yoshimatsu, and K. H.: *"Epidemiology and epizootiology of hantavirus infection in Japan."*; Jpn. J. Infect. Dis., 54, no. 3: 95-102 (2001).	
	CC	Bagdasarian MM, Nagai M, Frey J, Bagdasarian M: "*Immunogenicity of Actinobacillus ApxIA toxin eptiopes fused to the E. coli heat-labile enterotoxin B subunit*". Vaccine 17: 441-447. (1999).	
	CD	Bandivdekar, A.H., V.J. Vernekar, S.B. Moodbidri et al.: *"Characterization of 80 kDa human sperm antigen responsible for immunoinfertility." Am. J. Reprod. Immunol"*; 45, no. 1: 28-34 (2001).	
	CE	Becker D, Kemper E, Schell J, Masterson R: "*New plant binary vectors with selectable markers located proximal to the left T-DNA border. Plant Molecular Biology*"; *20*: 1195-1197 (1992).	
	CF	Berger, J., and S.L. Cain: *"Reproductive synchrony in brucellosis-exposed bison in the southern Greater Yellowstone Ecosystem and in noninfected populations."*; Conservation Biology, 13, no. 2: 357-366 (1999).	
	CG	Bosshardt, S.C., et al.: "*Brugia pahangi: circulating antibodies to adult worm antigens in uninfected progeny of homologously infected female jirds*"; Exp Parasitol, 72(4): p. 440-449 (1991).	
	CH	Cardenas L, Clements JD: "*Development of mucosal protection against the heat-stable enterotoxin (ST) of Escherichia coli by oral immunization with a genetic fusion delivered by a bacterial vector*"; Infect Immun 61: 4629-36 (1993).	
	CI	Chavali, S.R. and J.B. Campbell: "*Adjuvant effects of orally administered saponins on humoral and cellular immune responses in mice*"; Immunobiology, 174(3): p. 347-359 (1987).	
	CJ	Cousins, D.V.: *"Mycobacterium bovis infection and control in domestic livestock." Rev. Sci. Tech.*"; 20, no. 1: 71-85 (2001).	
	CK	Cox, J.C., and A.R. Coulter: "Adjuvants--a classification and review of their modes of	

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		action." Vaccine"; 15, no. 3: 248-256 (1997).	
	CL	Dalsgaard, K., et al.: "*Plant-derived vaccine protects target animals against a viral disease*". Nat Biotechnol, 15(3): p. 248-52 (1997).	
	CM	Dickinson, B.L. and J.D. Clements: "*Dissociation of Escherichia coli heat-labile enterotoxin adjuvanticity from ADP-ribosyltransferase activity*"; Infect Immun, 63(5): p. 1617-23 (1995).	
	CN	Dunbar, B.S., and S.V. Prasad: *"Contraceptive vaccine comprising a glycosylated 55KD zona pellucida protein immunogen and method of use of the same in contraception."* United States, 1997.	
	CO	Edelman, R. *"An update on vaccine adjuvants in clinical trial"*; AIDS Res. Hum. Retroviruses; 8, no. 8: 1409-1411 (1992).	
	CP	Fitchen J, Beachy RN, Hein MB: "*Plant virus expressing hybrid coat protein with added murine epitope elicits autoantibody response*"; Vaccine 13: 1051-7 (1995).	
	CQ	Frary A, Earle ED: "*An examination of factors affecting the efficiency of Agrobacterium-mediated transformation of tomato*"; Plant Cell Reports 16: 235-240 (1996).	
	CR	Hiatt AC, Cafferkey R, Bowdish K.: "*Production of antibodies in transgenic plants*"; Nature 342: 76-78 (1989).	
	CS	Hoshi, S., A. Uchino, N. Saito et al.: *"Comparison of adjuvants with respect to serum IgG antibody response in orally immunized chickens"*; Comp. Immunol. Microbiol. Infect. Dis., 22, no. 1: 63-69 (1999).	
	CT	Ingardia, C.J., et al., "*Correlation of maternal and fetal hepatitis B antibody titers following maternal vaccination in pregnancy*"; Am. J. Perinatology, 16(3): p. 129-132 (1999).	
	CU	Kennelly, J.J., and K.A. Converse: *"Surgical sterilization: an underutilized research procedure for wildlife damage control"*; In Proceeding of symposium: Contraception in wildlife management. Washington, D.C.: USDA/APHIS.	
	CV	Khoudi H, Laberge S, Ferullo J-M, Bazin R, Darveau A, Castonguay Y, Allard G, Lemieux R, Vezina L-P: "*Production of a diagnostic monoclonal antibody in perennial alfalfa plants. Biotechnology and Bioengineering*"; 64(2): 135-143 (1999).	
	CW	Koo, M., et al.: "*Protective immunity against murine hepatitis virus (MHV) induced by intranasal or subcutaneous administration of hybrids of tobacco mosaic virus that carries an MHV epitope*"; Proc Natl Acad Sci U S A, 96(14): p. 7774-9 (1999).	
	CX	Kuby, J. "*Immunolgy*"; Third ed., ed. Allen, D. New York: W. W. Freeman and Company, 1997.	
	CY	Leopold C.: "*A sweet way to keep proteins safe*"; Science. 281: 179 (1998)	
	CZ	Ma J.K.-C, Hein M.B. "*Plant antibodies for immunotherapy*"; Plant Physiol. 109: 341-346 (1995).	
	CA1	Marciani, D.J., J.B. Press, R.C. Reynolds et al.: *"Development of semisynthetic triterpenoid saponin derivatives with immune stimulating activity"*; Vaccine, 18, no. 27: 3141-3151 (2000).	
	CB1	Martinez, M.L., and J.D. Harris: *"Effectiveness of zona pellucida protein ZPB as an immunocontraceptive antigen"*; J. Reprod. Fertil., 120, no. 1: 19-32 (2000).	
	CC1	Mason H, Lam D, Arntzen CJ: "*Expression of hepatitis B surface antigen in transgenic plants*"; Proc. Natl. Acad. Sci. USA 89:11745-11749 (1992).	
	CD1	Mason HS, Ball J, Shi JJ, Jiang X, Estes MK, Arntzen CJ: "*Expression and immunogenicity of Norwalk virus capsid protein from transgenic tobacco and potáto*"; Proc. Natl. Acad. Sci. USA 93: 5335-5340 (1996).	
	CE1	Millar, S.E., S.M. Chamow, A.W. Baur et al.: *"Vaccination with a synthetic zona pellucida peptide produces long-term contraception in female mice"*; Science 246: 935-938 (1989).	
	CF1	Miller, L.A., B.E. Johns, and G.J. Killian: *"Immunocontraception of white-tailed deer with GnRH vaccine"*; Am. J. Reprod. Immunol. 44, no. 5: 266-274 (2000).	
	CG1	Miller, L.A., B.E. Johns, D.J. Elias et al.: *"Comparative efficacy of two immunocontraceptive*	

Examiner Signature		Date Considered	

Used in Lieu of PTO/SB/08A/B
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		vaccines"; Vaccine 15, no. 17-18: 1858-1862 (1997).	
	CH1	Modelska A, Dietzschold B, Sleysh N, Fu ZF, Steplewski K, Hooper DC, Koprowski H, Yusibov V: "*Immunization against rabies with a plant-derived antigen*"; Proc Natl Acad Sci U S A 95: 2481-5 (1998).	
	CI1	Murashige T, Skoog F: "*A revised medium for rapid growth and bioassays with tobacco tissue cultures*"; Physiologia Plantarum 15: 473-497 (1962).	
	CJ1	O'Dowd AM, Botting CH, Precious B, Shawcross R, Randall RE: "*Novel modifications to the C-terminus of LTB that facilitate site-directed chemical coupling of antigens and the development of LTB as a carrier for mucosal vaccines*"; Vaccine 17: 1442-1453 (1999).	
	CK1	O'Hern, P.A., Z.G. Liang, C.S. Bambra et al.: *"Colinear synthesis of an antigen-specific B-cell epitope with a 'promiscuous' tetanus toxin T-cell epitope: a synthetic peptide immunocontraceptive"*; Vaccine 15, no. 16: 1761-1766 (1997).	
	CL1	Pal, R., and O. Singh: *"Absence of corpus luteum rescue by chorionic gonadotropin in women immunized with a contraceptive vaccine"*; Fertil. Steril., 76 no. 2: 332-336 (2001).	
	CM1	Pillai D, Dixit A, Alok D, Garg LC: "*Translational fusion of heat labile enterotoxin chain B and beta- subunit of human chorionic gonadotropin: periplasmic expression in Escherichia coli and its immunogenicity*"; FEBS Lett 387: 23-6 (1996).	
	CN1	Richmond, M., and C.H. Conaway: *"Management breeding and reproductive performance of the vole, Microtus ochrogaster, in a laboratory colony"*; Laboratory Animal Care 19: 80-87 (1969).	
	CO1	Richter L, Thanavala Y, Arntzen CJ, Mason HS: "*Production of hepatitis B surface antigen in transgenic plants for oral immunization*"; Nature Biotechnol. 18:1167-1171(2000).	
	CP1	Sambrook J, Fritsch EF, Maniatis T: "*Molecular Cloning - A Laboratory Manual*"; Cold Spring Harbor Laboratory Press, Plainview, New York (1989).	
	CQ1	Schodel F, Will H, Johansson S, Sanchez J, Holmgren J: "*Synthesis in Vibrio cholerae and secretion of hepatitis B virus antigens fused to Escherichia coli heat-labile enterotoxin subunit B*"; Gene 99: 255-9 (1991).	
	CR1	Sewani CR, Bagdasarian MM, Ireland JJ, Bagdasarian M: "*Display of an inhibin epitope in a surface-exposed loop of the E. coli heat-labile enterotoxin B subunit*"; Vaccine 16: 1611-9 (1998).	
	CS1	Sixma TK, Kalk KH, van Zanten BAM, Dauter Z, Kingma J, Witholt B, Hol WGJ: "*Refined structure of Escherichia coli heat-labile enterotoxin, a close relative of cholera toxin*"; J. Mol. Biol. 230: 890-918 (1993).	
	CT1	Sixma TK, Pronk SE, Kalk KH, van Zanten BA, Berghuis AM, Hol WG: "*Lactose binding to heat-labile enterotoxin revealed by X-ray crystallography*"; Nature 355: 561-4 (1992).	
	CU1	Skinner, S.M., G.J. Killian, L.A. Miller et al.: *"Characterization of antigenicity and immunogenicity patterns of native and recombinant zona pellucida proteins in the white-tailed deer (Oidocoileus virginianus)"*; Journal of Reproduction and Fertility 101: 295-303 (1994).	
	CV1	Soltysik, S., J.Y. Wu, J. Recchia et al.: *"Structure/function studies of QS-21 adjuvant: assessment of triterpene aldehyde and glucuronic acid roles in adjuvant function"*; Vaccine 13, no. 15: 1403-1410 (1995).	
	CW1	Tacket CO, Mason HS, Losonsky G, Clements JD, Levine MM, Arntzen CJ: "*Immunogenicity in humans of a recombinant bacterial antigen delivered in transgenic potato*" Nature Medicine 4:607-609 (1998).	
	CX1	Tacket CO, Mason HS, Losonsky G, Estes MK, Levine MM, Arntzen CJ: "*Human immune responses to a novel Norwalk virus vaccine delivered in transgenic potatoes*"; J. Infect. Dis. 182: 302-305 (2000).	
	CY1	Takahashi, H., T. Takeshita, B. Morein et al.: *"Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs"*; Nature 344, no. 6269: 873-875 (1990).	

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	CZ1	Takikawa, M., M. Kamada, M. Maegawa et al.: *"Evaluation of two sperm antigens, rSMP-B and YWK-II, as targets for immunocontraception"* Zygote 9, no. 2: 145-151 (2001).	
	CA2	Tung, K.S.K., J. Ang, and Y. Lou.: *"ZP3 peptide vaccine that induces antibody and reversible infertility without autoimmune oophoritis"*; American Journal of Reproductive Immunology 35: 181-183 (1996).	
	CB2	VandeVoort, C.A., E.D. Schwoebel, and B.S. Dunbar: *"Immunization of monkeys with recombinant complimentary deoxyribonucleic acid expressed zona pellucida proteins"*; Fertil. Steril. 64, no. 4: 838-847 (1995).	
	CC2	Wada K, Aota S, Tsuchiya R, Ishibashi F, Gojobori T, Ikemura T: *"Codon usage tabulated from the GeneBank genetic sequence data"*; Nucleic Acid Research 18: 2367-2411 (1990).	
	CD2	Walmsley AM, Arntzen CJ: *"Plants for delivery of edible vaccines. Current Opinion in Biotechnology 11"*; 126-129 (2000).	
	CE2	Wigdorovitz A, Perez Filgueira DM, Robertson N, Carrillo C, Sadir AM, Morris TJ, Borca MV: *"Protection of mice against challenge with foot and mouth disease virus (FMDV) by immunization with foliar extracts from plants infected with recombinant tobacco mosaic virus expressing the FMDV structural protein VP1"*; Virology 264: 85-91 (1999).	
	CF2	Wigdorovitz, A., C. Carrillo, M.J. Dus Santos et al.: *"Induction of a protective antibody response to foot and mouth disease virus in mice following oral or parenteral immunization with alfalfa transgenic plants expressing the viral structural protein VP1"*; Virology 255, no. 2: 347-53 (1999).	
	CG2	Wu, J.Y., B.H. Gardner, C.I. Murphy et al.: *"Saponin adjuvant enhancement of antigen-specific immune responses to an experimental HIV-1 vaccine"*; J. Immunol. 148, no. 5: 1519-1525 (1992).	
	CH2	Yu, J. and W.H. Langridge: "A plant-based multicomponent vaccine protects mice from enteric diseases. Nat Biotechnol"; 19(6): p. 548-552 (2001).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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